IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

UMB Bank, N.A., as Trustee, Plaintiff, - against - SANOFI, Defendant.	No. 15 Civ. 08725 (GBD) (RWL)

PLAINTIFF'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT AS TO COUNTS I, II AND VII OF THE SECOND AMENDED COMPLAINT

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September 13, 2019

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Plaintiff UMB Bank, N.A., as Trustee ("Trustee") submits this memorandum in support of its motion for summary judgment as to Counts I, II and VII of the Second Amended Complaint.[1]

CASE SUMMARY AND SUMMARY OF ARGUMENT

While this case involves pharmaceutical products and a good deal of science and pharma-specific jargon and industry practice – and if the case were to be tried all of that and more would be presented at trial – the Trustee's present motion for summary judgment is straightforward, based on undisputed facts and demonstrates that, at the most fundamental of levels, Sanofi has breached the contract at issue.

In the summer of 2010, Sanofi, a French pharmaceutical company, made an unsolicited offer of $69 cash per share to acquire Genzyme, a U.S. biotech company. The Genzyme Board of Directors rejected the Sanofi offer as inadequate. Sanofi increased its offer to $74 cash per share, but Genzyme continued to find the offer inadequate. *See* UMB 56.1 ¶¶ 25-28.

As additional purchase consideration, Sanofi proposed issuing a security known as a contingent value right, or CVR, designed to facilitate a deal by bridging the acquisition price gap between the parties caused by (i) differences of opinion over the value of the Genzyme drug Lemtrada®, a potential blockbuster drug for the treatment of multiple sclerosis, and (ii) manufacturing issues affecting production of two of Genzyme's most successful drugs, Cerezyme® and Fabrazyme®. *See* UMB 56.1 ¶¶ 28-30.[2] The deal was struck. Sanofi agreed to

[1] Submitted herewith is a Statement of Undisputed Facts ("UMB 56.1"). A Table of Defined Terms is attached. Emphasis is added and internal citations are omitted unless otherwise specified. The Trustee reserves the right to seek reimbursement of its expenses as provided in the CVR Agreement.

[2] As summarized in an article by Sanofi's counsel: "A CVR is an instrument that requires an acquirer to pay additional consideration to the stockholders of a target company upon the occurrence of specified payment triggers. Its primary use is to bridge valuation gaps relating to contingent and other uncertain events that would impact the target company's value. . . . Payment on a CVR is tied to one or more specific triggers. . . . [M]any CVRs in pharmaceutical deals have payment triggers based on milestone achievements (such as Food and Drug Administration approval of new drugs) and financial performance metrics (such as

pay $74 cash ***and*** issue one CVR for each Genzyme share. The total cash price was over $20 billion. Approximately 291.4 million CVRs were issued at the time of the merger. The CVR Agreement is a contract between the Trustee, on behalf of the CVR Holders, and Sanofi, and is governed by New York law. The CVRs are securities publicly traded on Nasdaq. *See* UMB 56.1 ¶¶ 19, 22, 28, 31, 33, 35-36, 42.[3]

The CVR Agreement set out six Milestones, with potential for payment by Sanofi of an additional $14 cash per share (or an aggregate of $4.1 billion of acquisition consideration) equal to 20% of the total purchase price if all six Milestones were achieved. UMB 56.1 ¶¶ 46, 53-55.[4] This motion concerns only three of the six Milestones. Those are:

> **Approval Milestone**: CVR holders are entitled to receive $1 per CVR upon U.S. FDA approval of Lemtrada® for treatment of multiple sclerosis, if approval occurred on or before March 31, 2014.
>
> **Product Sales Milestone #1**: CVR holders are entitled to receive $2 per CVR in the event net sales for Lemtrada® total $400 million or more on a global basis during specified periods following product launch.
>
> **Production Milestone**: CVR holders are entitled to receive $1 per CVR in the event that Cerezyme® and Fabrazyme® production levels hit certain thresholds in calendar 2011.

See UMB 56.1 ¶¶ 47-48, 52.[5]

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drug sales)." Weil Gotshal, *The Deal Compass* at 2, 4 (November 2014), available at https://www.weil.com/~/media/files/pdfs/dealcompassnovember.pdf (last visited Sep. 12, 2019).

[3] *See* Joint Press Release, Sanofi and Genzyme, Sanofi-aventis to Acquire Genzyme for $74.00 in Cash Per Share Plus Contingent Value Right, (Feb. 16, 2019), available at https://www.prnewswire.com/news-releases/sanofi-aventis-to-acquire-genzyme-for-7400-in-cash-per-share-plus-contingent-value-right-116291094.html (last visited Sep. 12, 2019); Genzyme, Amendment No. 25 to SEC Form 14D-9 (Mar. 7, 2011) at 2, available at https://www.sec.gov/Archives/edgar/data/732485/000095012311022458/b85369sc14d9za.htm (last visited September 12, 2019).

[4] Five Milestones related to Lemtrada® (the Approval Milestone keyed to FDA approval of the product prior to March 31, 2014 and four Product Sales Milestones keyed to increasing levels of product sales) and one Milestone related to Cerezyme® and Fabrazyme® (the Production Milestone keyed to production of stated quantities of the two drugs in calendar year 2011). *See* UMB 56.1 ¶¶ 47-52.

[5] The Court dismissed without prejudice as unripe the Trustee's claims as to Product Sales Milestones #2-

In connection with the solicitation of shareholder approval for the merger, Genzyme estimated a **90% probability** of timely achieving the Approval Milestone, an **80% likelihood** of timely achieving Product Sales Milestone #1, and a **probable value of $5.58 for each of the 291.4 million CVRs – *i.e.*, a total CVR value of over $1.6 billion.** *See* UMB 56.1 ¶¶ 38-41. In its own communication with its own shareholders, Sanofi incorporated Genzyme's "description of the consideration" afforded by the CVRs. *See* UMB 56.1 ¶ 38(d).

The Milestones were not aspirational. They were the result of due diligence and negotiation by sophisticated parties. They were real, and they were achievable. In its SEC Form F-4 Registration Statement, Sanofi represented at the time the CVRs were issued that they provided Genzyme shareholders "the opportunity to participate in any future success of Lemtrada and the production in 2011 of both Cerezyme and Fabrazyme." UMB 56.1 ¶ 38(e).

In fact, Sanofi has achieved all three of the Milestones at issue on this motion – just not in the time frames required in the CVR Agreement to trigger payments to the CVR holders. As we demonstrate, Sanofi gamed the CVR Agreement.

Sanofi has managed to obtain FDA Approval and over $1.5 billion in sales of Lemtrada®, as well as a stable production and over $10 billion in sales of Cerezyme® and Fabrazyme®, and at the same time Sanofi has managed not to pay a penny more than the $74 per share that it had proposed and the Genzyme Board had rejected as inadequate and unfair to Genzyme shareholders.

As the Court has recognized,[6] the economic impact of achievement of the Milestones was potentially contrary to Sanofi's near-term financial interests, providing fertile ground for breach. For example, with respect to Product Sales Milestone #1, if Lemtrada® achieved $400 million in

4, which provide for additional payments of $10 per CVR. The Trustee reserves all rights.

[6] *See* Tr. of Aug. 17, 2016 Oral Arg. at 37–38 (ECF 77).

sales during a specified measurement period, Sanofi would be required to pay $584 million to the CVR holders ($2 times the number of CVRs), but if Lemtrada® achieved $399 million in sales during that period (even if later sales were much higher) Sanofi would be required to pay nothing on that Milestone. [redacted] But if achievement of the agreed-upon sales level triggering payment were delayed past the Milestone date, the CVR holders would be deprived of their financial bargain and Sanofi alone would retain all the financial benefits associated with product sales. Similar financial disincentives existed with respect to the Production Milestone and the Approval Milestone. *See* UMB 56.1 ¶¶ 47-48, 52, 147-148, 158.[7]

These financial disincentives were known and the parties contracted to impose on Sanofi mandatory, goal-directed efforts obligations to overcome them. That is not unusual in connection with CVR Agreements. As stated in an article authored by the Wachtell law firm, counsel for Genzyme in the merger with Sanofi: "Because an acquiror frequently can influence the payout on an event-driven CVR (such as through its investment and marketing efforts), targets negotiating CVRs often request provisions designed to align incentives. . . . In CVR instruments where the payout depends on FDA approval or other product development milestones, target companies often require the acquiror to undertake a specified level of efforts to achieve the milestones."[8] Sanofi

[7] If Sanofi achieved the required production in January 2012 rather than by December 31, 2011, it would have the benefits of having a supply of valuable drugs without paying the CVR holders anything. Similarly, Sanofi would benefit financially from achieving FDA approval after March 31, 2014 deadline because it would have the benefits of FDA approval without paying the CVR holders. *See* UMB 56.1 ¶¶ 47, 52.

[8] I. Kirman, and V. Goldfeld, *Contingent Value Rights (CVRs)* at 5, available at http://www.wlrk.com/webdocs/wlrknew/AttorneyPubs/WLRK.18405.11.pdf (discussing Sanofi CVRs). Parties "typically heavily negotiate" the efforts provisions in CVR Agreements. R. Murr, *Contingent Value Rights: a Middle Ground in M&A Boom* at 1 (Sept. 11, 2014), available at https://www.gibsondunn.com/wp-content/uploads/documents/publications/Murr-

and Genzyme, as parties across the table from each other, had financial interests that were, as Genzyme's counsel put it, "not perfectly aligned."[9] To compensate, the CVR Agreement imposed on Sanofi two mandatory specific obligations to use affirmative efforts "to achieve" the Milestones. Thus, Section 7.10 of the CVR Agreement requires that:

> [Sanofi] ***shall use*** Diligent Efforts ***to achieve*** the Approval Milestone and the Product Sales Milestones, and ***shall use*** commercially reasonable efforts ***to achieve*** the Production Milestone on a timely basis."

UMB 56.1 ¶¶ 56, 58. These efforts are mandatory ("shall use") and goal-directed ("to achieve the . . . Milestone[s]").[10]

The term "Diligent Efforts" is defined at length in the CVR Agreement, as follows:

> Diligent Efforts means with respect to the Product, efforts of a Person to carry out its obligations, and to cause its Affiliates and licensees to carry out their respective obligations, using such efforts and employing such resources normally used by Persons in the pharmaceutical business relating to the research, development or commercialization of a product, that is of similar market potential at a similar stage in its development or product life, taking into account issues of market exclusivity, product profile, including efficacy, safety, tolerability and convenience, the competitiveness of alternate products in the marketplace or under development, the availability of existing forms or dosages of alemtuzumab for other indications, the launch or sales of a biosimilar product, the regulatory environment and the profitability of the applicable product (including pricing and reimbursement status achieved) consistent with the Company's publicly reported financial statements (assuming the Company will not treat royalty payments to BSP [Bayer] as an expense for purposes of this clause, or the achievement

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ContingentValueRights.pdf (discussing Sanofi CVR Agreement).

[9] I. Kirman, R. Arsov, and A. Ment, *Contingent Value Rights: Bridging the Valuation Gap in M&A Deals* at 31 (September 8, 2011), available at http://www.wlrk.com/webdocs/wlrknew/AttorneyPubs/WLRK.18405.11.pdf (last visited Sep. 12, 2019) (discussing Sanofi CVR Agreement and noting that "payment of Production Sales Milestone #1, compared to revenue from the drug necessary to achieve the milestone, would cause net loss to Sanofi").

[10] In its SEC Form F-4 in connection with the issuance of the CVRs, Sanofi repeated its affirmative efforts obligations under Section 7.10 of the CVR Agreement and Sanofi summarized its ongoing reporting obligations to the Trustee under the CVR Agreement and that the Trustee was entitled to have an independent accountant verify the accuracy of the product sales information provided by Sanofi. *See* UMB 56.1 ¶ 14, 52. Sanofi refused to allow the product sales information that it has provided to the Trustee to be verified by an independent accountant. Sanofi's refusal raises serious red flags. The Court has held that the Trustee is entitled, as a matter of law, to an independent audit, but not during discovery in the litigation. *See* UMB 56.1 ¶¶ 14-15. The Trustee will pursue its audit rights.

> of Milestones in such a manner, that would reduce the profitability of the Product), and other relevant factors, including technical, commercial, legal, scientific and/or medical factors. Subject to the foregoing, "Diligent Efforts" shall include, but shall not be limited to, the following: (a) making expenditures in relation to the Product that are consistent with expenditures normally made by Persons in the pharmaceutical business in connection with products of similar market potential at similar stages in their development or product life; (b) implementing and maintaining appropriate Product and patient support services (including, but not limited to, risk identification and minimization programs and reimbursement support services); (c) initiating and completing all post-marketing approval commitments; (d) promptly seeking pricing approvals and/or minimally restrictive payer coverage decisions in the Major Markets; (e) fulfilling obligations under any copromotion agreement or arrangement with BSP [Bayer] should BSP [Bayer] exercise its right to co-promote the Product; (f) setting or seeking a commercial price for the Product that is consistent with the profile of the Product, including seeking premium pricing based on the effectiveness of the Product; (g) promoting the Product for all labeled multiple sclerosis indications; and (h) otherwise fulfilling the obligations of the Company and its Affiliates under Existing Licenses, including fulfilling obligations pursuant to the LAPA in order to maintain the rights to develop and commercialize the Product granted thereunder.

See UMB 56.1 ¶ 56. The phrase "commercially reasonable efforts" is not defined in the CVR Agreement, but is the subject of considerable judicial precedent.

In connection with the solicitation of shareholder approval of the merger, in public SEC filings Genzyme told its shareholders that:

> Following the close of the transaction, [Sanofi] will control the development, production and commercialization of Lemtrada, Cerezyme and Fabrazyme ***and will be obligated to take certain efforts to achieve*** the Approval Milestone, the Product Sales Milestones and the Production Milestone.

See UMB 56.1 ¶ 61. In its SEC Form-4 Registration Statement for the issuance of the CVRs, Sanofi told its own shareholders that it had these same obligations and quoted at length the CVR Agreement definition of Diligent Efforts. *See* UMB 56.1 ¶ 60.

Justice Cardozo's opinion in *Wood* v. *Lucy, Lady Duff-Gordon*, 222 N.Y. 88, 118 N.E. 214, 215-16 (1917), has influenced courts nationwide to follow the principle that:

> We are not to suppose that one party was to be placed at the mercy of the other. . . . [The] promise to pay the defendant one-half of the profits and revenues resulting from the

> exclusive agency and to render accounts monthly was a promise to use reasonable efforts to bring profits and revenues into existence.

In the CVR Agreement, Sanofi contracted – that is to say Sanofi undertook a duty to the Trustee – to use Diligent Efforts and commercially reasonable efforts "to achieve" the Milestones.

Because the CVR Agreement imposed upon Sanofi mandatory, goal-directed efforts obligations "to achieve" the Milestones,[11] Sanofi could not satisfy its obligations by ignoring the Milestones. But in fact Sanofi did just that. Chris Viehbacher, Sanofi's CEO who negotiated aspects of the merger, testified that he never read the CVR Agreement, never issued any instructions with respect to it, and is not aware of anyone who ever did. Viehbacher testified that, despite each Milestone having a fixed temporal deadline, the CVR agreement did not give Sanofi any "extra sense of urgency." UMB 56.1 ¶¶ 118-122. The Sanofi Board of Directors fired Viehbacher effective October 29, 2014 – two weeks before the FDA approved Lemtrada®. *See* UMB 56.1 ¶¶ 93, 337.

Serge Weinberg, Sanofi's Chairman, stepped in and was serving as Sanofi's CEO at the time of the US launch of Lemtrada®. Weinberg testified that he never read the CVR Agreement or any summary of it. Weinberg did not task anyone with overseeing compliance with the CVR Agreement, and he never considered the CVR Agreement in directing or prioritizing the allocation of Sanofi's resources. *See* UMB 56.1 ¶¶ 94-95, 123, 126-127.

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[11] Diligent is "[c]areful, attentive, and hardworking; persistent in doing something; industrious; assiduous … [c]arried out with care and steady effort." *Diligent*, BLACK'S LAW DICTIONARY (11th ed. 2019). Effort is "an attempt; an endeavor; a struggle directed to the accomplishment of an object." *Effort*, BLACK'S LAW DICTIONARY (4th ed. 1968). "*Merriam–Webster* defines 'effort' as a 'conscious exertion of power,' 'a serious attempt,' or 'something produced by exertion or trying.' . . . These definitions connote a conscious attempt to secure an outcome, or some affirmative action by the party required to exert efforts." *Holland Loader Co.* v. *FLSmidth A/S*, 313 F. Supp. 3d 447, 473 (S.D.N.Y. 2018) (Woods, J.), *aff'd*, 769 Fed. App'x. 40 (2d Cir. 2019) (interpreting contractual efforts obligation).

Olivier Brandicourt replaced Weinberg as Sanofi's CEO in April 2015. Brandicourt testified that he too never read the CVR Agreement or any summary of it, that he did not have a copy of it, [redacted]. Like Weinberg, [redacted]. *See* UMB 56.1 ¶¶ 96, 128-130.

Discovery in this action failed to identify *anyone* in management who was involved with product approval, product sales or product manufacturing – three areas of operations critically related to Sanofi's obligations under the CVR Agreement – who was informed of the mandatory efforts obligations that the CVR Agreement imposed upon Sanofi. *See* UMB 56.1 ¶¶ 118-144.

What discovery did reveal is that the only aspect of the CVR Agreement the Sanofi executives and employees were focused on was the financial burden that the achievement of the Milestones would represent. They talked about it and sought to avoid it. [redacted] UMB 56.1 ¶¶ 409-420.

As commonly said, timing is everything and a pillar of the CVR Agreement is timing. Missing the temporal deadlines set in the CVR Agreement is one way to not pay the CVR holders and avoid the financial burden on Sanofi. Discovery shows Sanofi's focus on timing and a clear repetitive pattern of missing the Milestones' temporal deadlines.

Undertaking mandatory affirmative efforts obligations and trumpeting the high percentage probability that the Milestones would be achieved, and then not informing those tasked with product approval, sales or manufacturing of the efforts that Sanofi was obligated to use and the temporal deadlines associated therewith – and not even considering the contract in deciding where to allocate Sanofi's resources – is not contract compliance. It is breach.

Sanofi cannot, and does not, dispute these facts. Instead, Sanofi hides behind the proposition that, as a public company, it has obligations to its shareholders and that, if its workforce just did its job, the efforts obligations of the CVR Agreement would be satisfied. But, if "business as usual" were sufficient, there would have been no need for sophisticated parties to define Diligent Efforts. It is absurd for Sanofi to suggest that the CVR Agreement means the same thing with or without Section 7.10 and the mandatory affirmative efforts clauses that Sanofi contracted to honor.

Beyond not informing its management and operations teams of the mandatory efforts they were committed to "use" and the temporal deadlines "to achieve," after Sanofi signed the CVR Agreement it took a series of affirmative actions that individually and collectively served to frustrate and prevent achievement of the Milestones. That too is breach, and while the Trustee is not under any obligation to prove an intentional breach, Sanofi's actions were intentional.

1. Sanofi breached its obligations with respect to the Approval Milestone. In connection with the solicitation of shareholder approval of the merger, the offering materials estimated a **90% probability** that Lemtrada® would timely achieve the Approval Milestone. *See* UMB 56.1 ¶ 39. But, immediately after acquiring Genzyme, Sanofi mandated massive across-the-board budget cuts. Despite its contractual obligation to use Diligent Efforts to achieve the Lemtrada®-related Milestones, no exception was made for Lemtrada®, nor was any analysis performed to determine if such cuts were consistent with Sanofi's performance obligations under the CVR Agreement. *See* UMB 56.1 ¶¶ 163.

To achieve the Approval Milestone, Sanofi needed to receive FDA approval on or before March 31, 2014 – which gave Sanofi three years from the merger with Genzyme to receive FDA approval. A conditional approval would have been sufficient. UMB 56.1 ¶ 367. But as soon as the merger closed, instead of going full steam on the application Sanofi [redacted]

[redacted]. UMB 56.1 ¶¶ 161, 164-173, 240-243, 256, 261-265. [redacted] UMB 56.1 ¶¶ 103, 209.

Sanofi knew it needed to invest in Lemtrada®. [redacted] UMB 56.1 ¶¶ 97-98, 255. [redacted] UMB 56.1 ¶¶ 161, 229.

[redacted], despite the fact that the CVR Agreement expressly prohibits Sanofi from doing this. The definition of Diligent Efforts (quoted in full at pages 4-5, *supra*) expressly prohibits Sanofi from factoring the CVR Milestones and other required royalty payments into projections of profit/loss, stating: ". . . the Company will not treat royalty payments to BSP [Bayer] as an expense for purposes of this clause, or the achievement of Milestones in such a manner, that would reduce the profitability of the Product . . . ." [redacted]

[redacted] *See* UMB 56.1 ¶¶ 161-173, 189, 252-254, 256, 261-265.

As a result of Sanofi's actions and inactions, on August 27, 2012 the FDA issued a Refuse To File ("RTF") Letter, the effect of which was to reject the Lemtrada® application because it could "not be considered as filed until all pertinent information and data ha[d] been received by the Food and Drug Administration." 21 C.F.R. § 601.2 (2018); UMB 56.1 ¶ 315. [redacted] *See* UMB 56.1 ¶¶ 92, 317. Despite being under a tight contractual deadline, Sanofi waited nearly five months to refile its Lemtrada® application. *See* UMB 56.1 ¶ 318. Thereafter, on December 27, 2013 the FDA issued a Complete Response Letter ("CRL") rejecting the Lemtrada® application on the merits. UMB 56.1 ¶ 320-321. [redacted] UMB 56.1 ¶ 324. It is rarer still for a sophisticated pharmaceutical manufacturer to receive both an RTF and a CRL on the same product.[12] Sanofi stated that it disagreed with the FDA's conclusions "and plans to appeal the agency's decision."[13] But Sanofi never filed any appeal, and time continued to pass. Sanofi eventually repackaged its Lemtrada® application, providing information to the FDA that it had all along, but that it had been holding back, and refiled it approximately two weeks after the March 31, 2014 Approval Milestone's deadline. UMB 56.1 ¶¶ 334-337, 362.

On November 14, 2014 – a short seven months after expiration of the time "to achieve" the Approval Milestone – the FDA approved Lemtrada®. Sanofi succeeded in having its approved

[12] Sanofi's expert could identify only one other instance of that ever happening. *See* UMB 56.1 ¶ 322.

[13] *See* Press Release, Sanofi-Genzyme, *Genzyme Receives Complete Response Letter from FDA on Lemtrada (alemtuzumab) Application* (Dec. 30, 2013), available at https://www.sanofigenzyme.com/en/about-us/newsroom/archive/2013/2013-12-30-01-02-00; UMB 56.1 ¶ 331.

product, without fulfilling its obligations under the CVR Agreement, and paid not a penny to the CVR holders for the Approval Milestone. *See* UMB 56.1 ¶¶ 337-362.

2. <u>Sanofi breached its obligation with respect to Product Sales Milestone #1.</u> Shortly after Sanofi missed the deadline for the Approval Milestone, attention shifted to purposeful avoidance of Product Sales Milestone #1.

[redacted] UMB 56.1 ¶¶ 1802, 182-183, 194.

[redacted] *See* UMB 56.1 ¶¶ 425-446.

Again, the key element was delayed timing. [redacted] *See* UMB 56.1 ¶¶ 492-493.

Sanofi seeks to excuse this manipulation with the suggestion that its finance staff was merely keeping track of a possible contingent liability. That suggestion is not supported by the

words of the contemporaneous emails. Indeed, when shown these same emails, Sanofi's CEO (Olivier Brandicourt) testified that looking for ways "**not to pay**" the CVR would be **"unethical."** UMB 56.1 ¶ 500. It is also breach.

Sanofi did reach the $400 million in sales but, through careful calendaring and planning, Sanofi succeeded in missing the deadline by which to achieve Product Sales Milestone #1. To date, Sanofi has realized over $1.5 billion from sales of Lemtrada®, but has not paid a penny on the CVRs. *See* UMB 56.1 ¶ 62.

3. Sanofi breached its obligations with respect to the Production Milestone. The production problems concerning Cerezyme® and Fabrazyme® were identified and investigated by Sanofi during its pre-deal diligence. Sanofi agreed to undertake commercially reasonable efforts to solve the production problems to achieve an agreed production level by a date certain.

In soliciting shareholder approval of its acquisition of Genzyme, Sanofi highlighted the production problems concerning Cerezyme® and Fabrazyme® and represented its scientific knowhow and ability to fix them as a benefit of the deal:

[redacted]

See UMB 56.1 ¶ 520.

But, with the Milestone deadline just 10 months away, [redacted] Sanofi's management and manufacturing personnel did not assist in restoring Genzyme's manufacturing processes to full production. *See* UMB 56.1 ¶¶ 528, 532.

On cross-examination by his own counsel, Sanofi's CEO sought to excuse [redacted] with the suggestion that the Genzyme workforce had just gone through a difficult period and needed to be left alone for morale purposes. *See* UMB 56.1 ¶ 529. Beyond being absurd, that is not a legal justification for breach of a contract to use mandatory efforts "to achieve the Production Milestone on a timely basis."

After doing nothing for four months, [redacted]. Sanofi alone enjoyed the financial benefits of increased production in 2012.

The Production Milestone was real and achievable. After doing nothing for 120 days at [redacted] Sanofi missed the deadline for the Production Milestone by just 90 days. *See* UMB 56.1 ¶¶ 528, 532, 545, 547. Sanofi enjoyed a stable supply of Cerezyme® and Fabrazyme® and has realized over $10 billion from sales of Cerezyme® and Fabrazyme®. Sanofi has not paid a penny on the CVRs. *See* UMB 56.1 ¶ 516.

4. The Milestones were negotiated by sophisticated parties, with every expectation that they were realistic and could be achieved. In soliciting shareholder approval for the merger, Sanofi and Genzyme publicly estimated a **90% probability** that Lemtrada® would timely achieve the Approval Milestone and an **80% likelihood** of timely achieving Product Sales Milestone #1, and they assigned a **$5.58 per CVR value** to the CVRs, indicating a high likelihood that each of the three Milestones presently at issue in this lawsuit would be achieved. UMB 56.1 ¶¶ 38-40.

Sophisticated parties are not presumed to agree to goals that are not achievable, and then misrepresent the prospect for success to shareholders and the SEC when soliciting proxy approval.

The achievement of the Milestones at issue simply required earnest, pro-active, good faith, and goal-directed efforts. Nothing super-human was required. In fact, Sanofi has achieved all three of the Milestones at issue on this motion – just not in the time frames required in the CVR Agreement to trigger payments to the CVR holders.

Had Sanofi used Diligent Efforts, had Sanofi earnestly tried "to achieve" the Milestones, the Milestones would have been (as they later were) achieved. But Sanofi did less than nothing. Sanofi failed to inform its workforce of what was required of them, and Sanofi acted in a manner to avoid achievement of the Milestones.

Sanofi succeeded in buying Genzyme for a price rejected by Genzyme as inadequate, benefiting from Lemtrada®, Cerezyme® and Fabrazyme® bringing in over $ 11.5 billion in sales, and paying not a penny to the CVR holders. *See* UMB 56.1 ¶¶ 62-63.[14]

The relevant facts are undisputed. Sanofi breached its mandatory efforts obligations. There is no triable issue as to damages; the cash payments due for the achievement of each Milestone are specifically set forth in the CVR Agreement.

THE UNDISPUTED FACTS

The undisputed facts relevant to determination of this motion are set forth in detail in Plaintiff UMB's accompanying Rule 56.1 Statement.

APPLICABLE LEGAL STANDARD

Summary judgment is to be granted if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a). The opposing

[14] [redacted] As Sanofi's CEO testified, one would only do that if it thought the Milestones were realistically achievable and the CVRs were worth more than the re-purchase price. [redacted] UMB 56.1 ¶¶ 154-157.

party must set out specific facts showing a genuine issue for trial, and cannot "rely merely on allegations or denials" contained in the pleadings. "Once the moving party has asserted facts showing that the non-movant's claims cannot be sustained, the opposing party must set out specific facts showing a genuine issue for trial, and cannot rely merely on allegations or denials contained in the pleadings." *Guzik* v. *Albright*, 2018 WL 4386084, at *2 (S.D.N.Y. Sept. 14, 2018). A fact is "material" only "if it may impact the outcome of the suit under the governing law," and "[a] dispute of a material fact is 'genuine' only 'if the evidence is such that a reasonable jury could return a verdict for the non-moving party.'" *Hudson Bay Master Fund Ltd.* v. *Patriot Nat'l, Inc.*, 2019 WL 1649983, at *6 (S.D.N.Y. Mar. 28 2019) (Daniels, J.) (quoting *Anderson* v. *Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)).

New York law governs the CVR Agreement. *See* CVR Agreement § 1.10.

> Under governing New York law, agreements must be "construed in accord with the parties' intent." *Greenfield* v. *Philles Records, Inc.,* 98 N.Y.2d 562, 569 (2002). The terms of an agreement provide the best evidence of what the parties intend, and "a written agreement that is complete, clear[,] and unambiguous on its face must be enforced according to the plain meaning of its terms." *See id.* Furthermore, "we do not consider particular phrases in isolation, but rather interpret them in light of the parties' intent as manifested by the contract as a whole." *Gary Friedrich Enterps., LLC* v. *Marvel Characters, Inc.,* 716 F.3d 302, 313 (2d Cir. 2013). . . .

Abdullayeva v. *Attending Homecare Services LLC*, 928 F.3d 218, 222 (2d Cir. 2019). Where "a contract is straightforward and unambiguous, its interpretation presents a question of law for the court to be made without resort to extrinsic evidence." *Spinelli* v. *National Football League*, 903 F.3d 185, 200 (2d Cir. 2018). "[U]nder New York law, an action for breach of contract requires proof of (1) a contract, (2) performance of the contract by one party; (3) breach by the other party;

and (4) damages." *Rexnord Holdings, Inc*. v. *Bidermann*, 21 F.3d 522, 525 (2d Cir. 1994). Here, the only issue to be litigated is whether Sanofi breached the CVR Agreement.[15]

Sanofi has achieved all three of the Milestones at issue on this motion – just not in time. It is settled in this Circuit that, once the Trustee proves that Sanofi breached the CVR Agreement and the breach would be expected to have caused the damages, the burden shifts to the Sanofi to show that its conduct did not cause damages. *See Bloor* v. *Falstaff Brewing Corp.*, 601 F.2d 609, 614-15 (2d Cir. 1979) (Friendly, J.) (interpreting contractual efforts obligation and finding that once plaintiff proved breach of contract the burden shifted to the defendant to prove that it would have required extraordinary efforts to avoid causing damages – party may demonstrate "best efforts" were made by proving "there was nothing significant it could have done" to meet its obligations "that would not have been financially disastrous"); *Aeronautical Indus. Dist. Lodge 91 of Inter. Ass'n. of Machinists and Aerospace Workers* v. *United Technologies Corporation*, 230 F.3d 569, 578 (2d Cir. 2000) (interpreting contractual efforts provision and finding that once plaintiff proved breach of contract the burden shifted to the defendant to prove that there was "nothing significant it could have done" to avoid causing damages) (citing *Bloor*, 601 F.2d at 614-615).

The *Restatement (Second) of Contracts* § 245 cmt. b (Am. Law Inst. 1981) recognizes this shifting in burden:

> Although it is implicit in the rule that the condition has not occurred, it is not necessary to show that it would have occurred but for the lack of cooperation. It is only required that the breach have contributed materially to the non-occurrence. Nevertheless, if it can

[15] Sanofi's counsel has issued a legal opinion that the CVR Agreement was duly authorized, executed and delivered by Sanofi. *See* Sanofi-Aventis, Amendment No. 3 to Form F-4 Registration Statement Under the Securities Act of 1933, at 39 (filed Mar. 28, 2011), Exhibit 5.2 Opinion of Weil Gotshal & Manges, https://www.sec.gov/Archives/edgar/data/1121404/000119312511079792/dex52.htm. There is no issue as to the Trustee's performance. There is no issue as to quantum of damages, which is set by the fixed Milestone payments in the CVR Agreement. *See* UMB 56.1 ¶¶ 47-48, 52.

> be shown that the condition would not have occurred regardless of the lack of cooperation, the failure of performance did not contribute materially to its non-occurrence and the rule does not apply. ***The burden of showing this is properly thrown on the party in breach.***

ARGUMENT

I. The CVR Requires Sanofi to Take Pro-Active, Good Faith, Goal-Directed Efforts to Achieve the Milestones.

The CVR Agreement requires, at an absolute minimum, that Sanofi take steps "to achieve" each of the three temporal Milestones. Sanofi could not ignore the Milestones, and it could not simply continue with business as usual. *See Bloor*, 601 F.2d at 614 (finding that efforts clause requires defendant to do more than treat plaintiff's brand as well as it treated its own brands); *Holland Loader Co.* v. *FLSmidth A/S*, 313 F. Supp. 3d 447, 473 (S.D.N.Y. 2018) (Woods, J.), *aff'd*, 769 Fed. App'x. 40 (2d Cir. 2019) ("compliance with a 'commercially reasonable efforts' clause requires at the very least some conscious exertion to accomplish the agreed goal"). A contrary interpretation, allowing Sanofi to conduct business as usual, would render superfluous the mandatory efforts obligations to achieve the Milestones.

II. The Relevant Facts Are Undisputed that Sanofi Failed to Take Pro-Active, Good Faith, Goal-Directed Efforts to Achieve the Milestones.

Sanofi breached the CVR Agreement by failing to undertake affirmative efforts to achieve the Milestones. Sanofi's CEO testified that the CVR agreement did not give him "an extra sense of urgency." UMB 56.1 ¶ 122. It should have. Sanofi had obligations keyed to temporal deadlines.

No one at Sanofi instructed the personnel responsible for securing FDA approval for Lemtrada®, selling Lemtrada® or producing Cerezyme® and Fabrazyme® as to the goals to be achieved and what efforts the CVR Agreement required. UMB 56.1 ¶¶ 118-144. The only Sanofi personnel who did consider the CVR Agreement were those who were charged with financial

reporting [redacted] *See* UMB 56.1 ¶¶ 409-415, 425-438. Sanofi viewed the Milestone payments as a risk to be mitigated, not an obligation to be achieved.

A. Sanofi Failed to Use Required Efforts to Achieve the Approval Milestone

Sanofi breached the CVR Agreement by failing to take specific efforts to achieve the Approval Milestone. From the c-suite, to finance, to those working on the Lemtrada® application, no one at Sanofi determined what Diligent Efforts to achieve the Approval Milestone required, let alone ensured those obligations were fulfilled. *See* UMB 56.1 ¶¶ 119-144. Sanofi's Global Head of Research and Development, Elias Zerhouni, testified that he was not provided with a copy of the CVR Agreement or any instructions as to Sanofi's Diligent Efforts obligations under it. UMB 56.1 ¶¶ 99-100, 132. Stephen Lake, the lead statistician on the Lemtrada® application, had no discussions with anyone at Sanofi concerning the CVR Agreement. UMB 56.1 ¶¶ 108, 139. Michael Panzara, who oversaw FDA approval of Lemtrada®, was given no instructions as to what was required to comply with the CVR Agreement. UMB 56.1 ¶¶ 110, 140.

Rather than taking conscious, goal-oriented steps to secure timely FDA approval for Lemtrada®, [redacted]. UMB 56.1 ¶¶ 161, 164 -165, 169-173, 262-263, 264-265, 287, 319-320, 334-337, 338-359.

[redacted] *See* UMB 56.1 ¶ 306. [redacted] UMB 56.1 ¶ 307. For certain patients, it is "**as close to a cure as anyone wants to use the C [cure] word**." UMB 56.1 ¶ 74. To ensure Lemtrada® reached its

blockbuster potential, [redacted] UMB 56.1 ¶¶ 252-256, 261-265. [redacted] UMB 56.1 ¶¶ 84, 293.

[redacted] UMB 56.1 ¶¶ 164, 206. That is the opposite of using Diligent Efforts to reach the Approval Milestone. That is breach.

Sanofi seeks to excuse its conduct by reference to its normal budgeting process. It was not normal by any measure. [redacted] *See* UMB 56.1 ¶¶ 161-173. [redacted] UMB 56.1 ¶ 225. [redacted] UMB 56.1 ¶¶ 189, 202. [redacted] UMB 56.1 ¶ 202. The discovery record confirms that Lemtrada® was the only drug that Sanofi subjected to this type of budgeting analysis. *See* UMB 56.1 ¶ 185.

These decisions inflicted a severe blow to Lemtrada®'s potential. [redacted] UMB 56.1 ¶¶ 110, 205.

[redacted] UMB 56.1 ¶¶ 214, 263. [redacted] UMB 56.1 ¶¶ 103, 209. That is breach.

These budget cuts curbed Lemtrada®'s potential. They conflicted with Sanofi's obligation to take conscious, goal-oriented efforts "to achieve" the Approval Milestone. [redacted] *See* UMB 56.1 ¶ 152. That is breach. *See Bloor*, 601 F.2d at 614-15 (under New York law a party breaches its "best efforts" covenant when it places its own economic interest above its contractual obligations).

Sanofi also breached the CVR Agreement by failing to use Diligent Efforts to address a well-known and critical concern in Lemtrada®'s application for FDA approval, for which it had more than a year to do if it was trying to meet the Milestone. [redacted] *See* UMB 56.1 ¶¶ 321, 338 – 339, 340, 356. The concern was resolvable (and ultimately was resolved), but not until multiple rounds of denials and long timelines for resubmission by a team that was not advised of any particular deadline. Bias can skew a drug trial's results, suggesting a product is safe and effective when it is not. UMB 56.1 ¶ 295. [redacted] UMB 56.1 ¶¶ 299-300, 327, 349-352. [redacted]

[redacted][16] [redacted] *See* UMB 56.1 ¶¶ 335-336, 357-359. Sanofi was well aware of this issue.

- At the time, the multiple sclerosis community recognized the importance of screening EDSS scores in multiple sclerosis trials. UMB 56.1 ¶¶ 343-344.
- [redacted] UMB 56.1 ¶¶ 345-346.
- [redacted] Dr. Sharon Yan, expressed the same concern about screening EDSS scores in the context of approving another multiple sclerosis drug, Tysabri®. UMB 56.1 ¶¶ 341-342.
- [redacted] UMB 56.1 ¶ 340. [redacted] UMB 56.1 ¶ 339.
- [redacted] UMB 56.1 ¶¶ 347; *see also* 348 – 353.

Sanofi had the necessary data in hand and had every opportunity to address the bias issue with the FDA. [redacted] *See* UMB 56.1 ¶¶ 335-337, 357-359, 362. As Sanofi's CEO, Christopher Viehbacher, stated in an investor call on October 28, 2014, "if the FDA does not approve a product straight away, even if you get it approved elsewhere, there is still a 'waiting to see what the FDA does.'" UMB 56.1 ¶ 360.

[16] An EDSS score, is a subjective measurement used to assess the health of a patient with multiple sclerosis. A screening EDSS score is taken at the time when it is determined whether a patient will participate in the study but before she is assigned the drug she is being treated with. A baseline EDSS score, which is the score Sanofi focused on, is taken just before the patient's initial dose of the drug. UMB 56.1 ¶¶ 304-305.

Sanofi not only sabotaged its application on the substance by providing incomplete information, it also dragged its feet to take any corrective actions when asked for additional information by the FDA. But shortly after the Approval Milestone's deadline had passed, Sanofi ramped up the activity and provided the information that the FDA had been requesting, which led the FDA to approve the revised application in under seven months. *See* UMB 56.1 ¶¶ 332-337.

Sanofi had its FDA-approved product, but it had manipulated the timing of FDA review and succeeded in missing the Approval Milestone. *See* UMB 56.1 ¶¶ 331-362 .

B. Sanofi Failed to Use Required Efforts to Achieve Product Sales Milestone #1

Sanofi used the same trick with Product Sales Milestone #1. Rather than abide by its Diligent Efforts contractual obligation to take conscious, pro-active steps "to achieve" the Milestone, Sanofi acted to frustrate the achievement of Product Sales Milestone #1. The sales required by Production Sales Milestone #1 were achieved – just too late to trigger the Milestone payment.

No one at Sanofi instructed those responsible for selling Lemtrada® as to what they needed to do to comply with its Diligent Efforts obligations to achieve Product Sales Milestone #1, or developed a program for ensuring those obligations were satisfied. Sanofi's Vice President of Global Commercial Strategy for multiple sclerosis, Mark Underwood, stated that he was never told that Sanofi was under a contractual obligation to use specific efforts, much less Diligent Efforts, to achieve the Milestone. The person responsible at Sanofi for launching Lemtrada® in the United States never read or discussed the CVR Agreement with anyone. The person responsible for launching Lemtrada® in Europe had never heard of any Diligent Efforts obligation. *See* UMB 56.1 ¶¶ 138, 142-144.

Those responsible for marketing and selling Lemtrada® proceeded as they would have in the ordinary course and without taking any pro-active efforts "to achieve" Product Sales Milestone #1. The team responsible for launching Lemtrada® in Europe, which had no idea what the CVR Agreement required, [redacted] UMB 56.1 ¶¶ 142, 380-392. As a result of this total disregard for the CVR Agreement and in derogation of its mandatory obligations to use Diligent Efforts to achieve Product Sales Milestone #1, a pricing strategy that would cause Sanofi to miss the Milestone was implemented, and the Milestone was missed. *See* UMB 56.1 ¶¶ 396-401. That is breach.

Sanofi was looking for ways that "**would allow us <u>not</u> to pay the CVR**", conduct that Sanofi's CEO (Olivier Brandicourt) called **"<u>unethical</u>."** UMB 56.1 ¶ 500. [redacted] These were not standard budgeting decisions as Sanofi contends. [redacted] in violation of the plain language of the CVR Agreement, *see supra* Part II, [redacted] UMB 56.1 ¶ 502. That too is breach. *See Bloor*, 601 F.2d at 614-15 (under New York law a party breaches its "best efforts" covenant when it places its own economic interest above its contractual obligations).

C. Sanofi Failed to Use Required Efforts to Achieve the Production Milestone

Sanofi was obligated to "use commercially reasonable efforts to achieve the Production Milestone on a timely basis [*i.e.*, by December 31, 2011]." But no one at Sanofi provided instruction, guidance or operational support to those responsible for producing Cerezyme® and Fabrazyme®. Sanofi's Global Head of Manufacturing testified that the "**CVR targets were never mentioned to me.**" UMB 56.1 ¶¶ 58, 530. That is breach.

In soliciting shareholder votes for the transaction, Sanofi's CEO, Chris Viehbacher [redacted] UMB 56.1 ¶ 522. But far from acceleration, as soon as the deal closed [redacted] UMB 56.1 ¶ 528.

As Sanofi admitted at the time, [redacted] UMB 56.1 ¶ 526. [redacted] is the antithesis of the good faith efforts that Sanofi was obligated to use and shows just how tainted all of Sanofi's actions were with regards to the Milestones. *See Bloor*, 601 F.2d at 614-15.

In August 2012, [redacted], Sanofi changed its tune when it realized that if it continued doing nothing it would put its own 2012 financial projections in jeopardy. UMB 56.1 ¶¶ 539-543. Only then did Sanofi take its foot off the brakes and apply its considerable knowledge and resources to increase production. The production problems were solved, and production was restored – but 90 days too late to trigger payments to CVR holders.

The Court need go no further to conclude that Sanofi breached the CVR and summary judgment should be entered on that legal issue irrespective of causation, which is discussed below.

III. Sanofi's Breaches Caused It to Miss the Milestones.

The undisputed facts demonstrate that Sanofi breached the CVR Agreement through its failure to use Diligent Efforts to achieve the Approval Milestone and Product Sales Milestone #1, and its failure to use commercially reasonable efforts to achieve the Production Milestone. The undisputed facts also demonstrate that those breaches would be expected to cause Sanofi to miss the Milestones.

A. As a Matter of Law, Plaintiff Need Only Show that Sanofi's Breaches Would Be Expected to Cause Sanofi to Miss the Milestones

In cases involving breach of a contractual efforts clause, the plaintiff's burden as to causation is limited to demonstrating that defendant's breach would be expected to cause damages. *See Bloor*, 601 F.2d at 615 (2d Cir. 1979) (Friendly, J.).

In *Bloor*, the defendant breached a contract requiring it to "use its best efforts to promote and maintain a high volume of sales." *Id.* at 610. Judge Friendly stressed that "[p]laintiff was not obliged to show just what steps [defendant] could reasonably have taken to maintain a high volume for [the plaintiff's] products" to prove that defendant did not use best efforts. *Id.* at 614. Once the plaintiff showed that defendant "simply didn't care about [the sales] volume" and was focused instead on what "was best for Falstaff's overall profit picture," the plaintiff had satisfied its burden to prove that the breach of the contract caused its damages. *Id.* at 614. At that point, "[t]he burden then shifted to [the defendant] to prove there was nothing significant it could have done to promote [the plaintiff's] sales that would not have been financially disastrous." *Id.* at 614-15.

In *Aeronautical Indus. Dist. Lodge 91*, 230 F.3d at 578 (2d Cir. 2000), the Circuit similarly interpreted a contractual efforts provision, finding that once plaintiff proved breach of contract the burden shifted to the defendant to prove that there was "nothing significant it could have done" to avoid causing damages; citing *Bloor*, 601 F.2d at 614. To hold otherwise, would impose the undue

burden on the party to the contract — who had no control over or insight into the breaching party's decision-making process — of proving what the breaching party should or should not have done. *See Restatement (Second) of Contracts* § 245 cmt. b (Am. Law Inst. 1981), quoted at p. 15, *supra*.

The inaction and actions of Sanofi to frustrate achievement of the Milestones set forth above and detailed in the accompanying Rule 56.1 Statement, are sufficient, as a matter of law, to shift the burden to Sanofi to show that only extraordinary efforts could have achieved any Milestone. Sanofi cannot sustain its burden. The Trustee is entitled to summary judgment.

B. Sanofi Missed the Approval Milestone Because It Breached Its Obligations

Sanofi missed the Approval Milestone because of Sanofi's breach of its Diligent Efforts obligations (1) by submitting an incomplete application form; (2) by canceling budgeted and approved studies; (3) refusing to perform a screening EDSS analysis before the FDA denied the Lemtrada® application; and (4) delaying its additional submissions to the FDA when requested.

1. Sanofi's Incomplete Application Caused It to Miss the Approval Milestone.

Sanofi filed its Lemtrada® application on June 8, 2012. Two months later the FDA issued an RTF because the application was not properly formatted. That never should have happened and it took Sanofi almost four months to fix the application. *See* UMB 56.1 ¶¶ 314-318. Sanofi's failures delayed the approval of the Lemtrada® application by more than five months causing it to miss the Approval Milestone.

2. Sanofi's Cancelation of Studies Caused It to Miss the Approval Milestone.

The FDA denied the Lemtrada® application in December 2013. UMB 56.1 ¶¶ 318 – 319. Thereafter, the FDA said it would approve the application on a conditional basis [redacted]. A conditional approval would have been sufficient to meet the Approval Milestone. UMB 56.1 ¶¶ 364-368. But, over the objection of its

MS team, [redacted]. *See* UMB 56.1 ¶¶ 161-173, 253, 262-264, 363. [redacted] Lemtrada® would have been approved before the deadline, thereby triggering the Approval Milestone payment.

3. Sanofi's Failure to Perform the Screening EDSS Analysis Caused It to Miss the Approval Milestone.

In November 2014, the FDA approved Lemtrada® [redacted] that confirmed Lemtrada® was a safe and effective drug. Sanofi breached the CVR Agreement by refusing to perform this analysis before the initial denial of the application in December 2013. *See* UMB 56.1 ¶¶ 337-362. Had Sanofi performed the analysis when it should have, the application would not have been denied in December 2013, and Sanofi would have met the Approval Milestone.

4. Sanofi's Delay in its Submission Caused it to Miss the Approval Milestone.

It took Sanofi more than five months to resubmit the Lemtrada® application because it failed to submit a complete application. And it took Sanofi more than four additional months after receipt of the CRL to start submitting information in response to the CRL. *See* UMB 56.1 ¶¶ 314-319, 334. With this nine months of delay, Sanofi missed the Approval Milestone by only seven months. *See* UMB 56.1 ¶¶ 47, 314-319, 334. Sanofi owes $1 per CVR plus prejudgment interest[17] from January 28, 2014.[18]

[17] The CVR Agreement provides the interest rate to be applied to payments due to the CVR holders in the event of a breach. *See* CVR Agreement § 1.1 ("Breach Interest Rate"). Breach Interest Rate is defined to mean "a per annum rate equal to the prime rate of interest quoted by Bloomberg, or similar reputable data source, plus three percent (3%), calculated daily on the basis of a three hundred sixty-five (365) day year or, if lower, the highest rate permitted under applicable law." *See* UMB 56.1 ¶¶ 44-45.

[18] In its SEC Form F-4 filed in connection with the issuance of the CVRs, Sanofi summarizes the "Payment Dates" for each Milestone. The latest payment date for the Approval Milestone is 20 business days after achievement of such milestone. *See* UMB 56.1 ¶ 47. *See* footnote 17 concerning prejudgment interest.

C. Sanofi Missed Product Sales Milestone #1 Because It Breached Its Obligations

From the time Sanofi acquired Genzyme in March 2011 through at least the spring of 2014, Sanofi's internal projections were that it would meet Product Sales Milestone #1. *See* UMB 56.1 ¶¶ 153, 156, 412, 428. Then Sanofi looked for ways not to pay the Milestone.

- [redacted]
- [redacted]
- [redacted]

See UMB 56.1 ¶¶ 409-414, 431-434, 493. [redacted] and Sanofi missed Product Sales Milestone #1. *See* UMB 56.1 ¶ 488. Sanofi owes $2 per CVR plus prejudgment interest from March 11, 2016.[19]

D. Sanofi Missed the Production Milestone Because It Breached Its Obligations

In soliciting shareholder approval of its acquisition of Genzyme, Sanofi highlighted the production problems concerning Cerezyme® and Fabrazyme® and represented its scientific knowhow and ability to fix them – a fix that would deliver additional value to Genzyme shareholders through the CVRs. But, with the ink on the CVR Agreement barely dry, [redacted] Sanofi

[19] In its SEC Form F-4 filed in connection with the issuance of the CVRs, Sanofi summarizes the "Payment Dates" for each Milestone. The latest payment date for Product Sales Milestone #1 is 20 business days after notice of achievement of such milestone. *See* UMB 56.1 ¶ 48. *See* footnote 17 concerning prejudgment interest.

withheld its knowhow and ability to fix the production problems for over four months. When Sanofi finally engaged, it missed the deadline for the Production Milestone by only 90 days. *See* UMB 56.1 ¶¶ 545, 547. Simple math instructs that if commercially reasonable efforts to address the production issues post-closing had been made, the Milestone would have been achieved with weeks to spare. Sanofi owes $1 per CVR plus prejudgment interest from January 30, 2012.[20]

CONCLUSION

The Court should enter summary judgment in favor of the Trustee on Counts I, II and VII of the Second Amended Complaint, and order Sanofi to pay the Trustee $4 per CVR, plus prejudgment interest at the contract Breach Interest Rate from date of breach.

Dated: September 13, 2019

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[20] In its SEC Form F-4 filed in connection with the issuance of the CVRs, Sanofi summarizes the "Payment Dates" for each Milestone. The latest payment date for the Production Milestone is 20 business days after January 3, 2012. *See* UMB 56.1 ¶ 52. *See* footnote 17 concerning prejudgment interest.

TABLE OF DEFINED TERMS

TERM	DEFINITION
Approval Milestone	refers to the CVR Agreement provision that entitles CVR holders to receive $1 per CVR after "receipt by the Company or one of its Affiliates, on or before March 31, 2014, of the FDA Approval of alemtuzumab [Lemtrada®] for treatment of multiple sclerosis."
Bayer, BSP	refer to Bayer Schering Pharma AG.
Breach Interest Rate	means the interest rate to be applied to payments due to the CVR holders in the event of a breach as defined in the CVR Agreement § 1.1.
CEO	means Chief Executive Officer.
Cerezyme®	refers to imiglucerase, a recombinant enzyme replacement for the treatment of Gaucher disease.
CFO	means Chief Financial Officer.
Chairman	means Chairman of the Board of Directors.
commercially reasonable efforts	refers to the required obligation of effort with respect to the Production Milestone as set forth in the CVR Agreement § 7.10.
Second Amended Complaint	refers to the second amended complaint filed August 29, 2017 in this litigation.
CRL	refers to a "Complete Response Letter" from the FDA.
CVR	refers to a Contingent Value Right, an instrument requiring an acquirer to pay additional consideration to the holder upon the occurrence of specified triggering events.
CVR Agreement	refers to the Contingent Value Rights Agreement by and between Sanofi-Aventis and American Stock Transfer & Trust Company, LLC, Dated as of March 30, 2011.

Defendant	refers to Sanofi, a global pharmaceutical company incorporated under the laws of France as a société anonyme.
Diligent Efforts	refers to the required obligation of effort with respect to the Approval Milestone and Product Sales Milestones as set forth in the CVR Agreement § 7.10.
EDSS	refers to the Expanded Disability Status Scale, a subjective measurement used to assess the health of a patient with multiple sclerosis.
Fabrazyme®	refers to agalsidase beta, a recombinante enzyme replacement therapy for the treatment of Fabry Disease.
FDA	refers to the U.S. Food and Drug Administration.
Genzyme	refers to Genzyme Corporation, a biotechnology corporation acquired by Sanofi in 2011 and now a wholly-owned subsidiary of Sanofi.
Lemtrada®	refers to alemtuzumab, a CD52-directed cytolytic monoclonal antibody for the treatment of relapsing multiple sclerosis.
Merger Agreement	refers to the February 16, 2011 Agreement and Plan of Merger among Sanofi-Aventis, GC Merger Corp. and Genzyme Corporation.
Milestone(s)	refers to the triggering events for a payment to holders under the CVR Agreement, specifically, any of the Approval Milestone, Product Sales Milestones, and the Production Milestone.
MS	refers to multiple sclerosis, a disease of the central nervous system.
Nasdaq	means the Nasdaq stock exchange.
Plaintiff or Trustee	refers to UMB Bank, N.A., a federally-chartered national banking organization with a principal place of business in Kansas City, Missouri.

Product Sales Milestone #1	refers to the CVR Agreement provision that entitles CVR holders to receive $2 per CVR in the event "the sum of (x) the aggregate Major Market Product Sales for each Qualifying Major Market plus (y) the aggregate Product Sales achieved in all countries that are not Qualifying Major Markets during the four (4)-calendar quarter period that begins on the first anniversary of Product Launch equals or exceeds a total of four hundred million dollars."
Product Sales Milestones	means each of (a) Product Sales Milestone #1, (b) Product Sales Milestone #2, (c) Product Sales Milestone #3 and (d) Product Sales Milestone #4.
Production Milestone	refers to the CVR Agreement provision that entitles CVR holders to receive $1 per CVR in the event that Cerezyme® and Fabrazyme® production levels achieve certain thresholds in calendar year 2011.
RTF	refers to a "Refuse to File" letter from the FDA.
Sanofi	refers to refers to Sanofi, a multinational pharmaceutical company incorporated under the laws of France as a *société anonyme*.